



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/620,287 | 07/15/2003 | Patrick J. Sweeney | 029815-0102 | 7722 |

23524 7590 11/01/2006

FOLEY & LARDNER LLP
150 EAST GILMAN STREET
P.O. BOX 1497
MADISON, WI 53701-1497

| |
|----------|
| EXAMINER |
|----------|

KOHARSKI, CHRISTOPHER

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

3763

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/620,287

Applicant(s)

SWEENEY, PATRICK J.

Examiner

Christopher D. Koharski

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 18-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 1/3/05, 7/6/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application.
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 18-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group and species (Group I, Species A selected), there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/11/2006. For the purposes of expedient examination Examiner will include claims 1-17 for examination in this application.

Information Disclosure Statement

The information disclosure statements (IDS) that were submitted on 1/03/2005 and 7/06/2006 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statements.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 and 13-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Grayson (6,210,376). Grayson discloses a cannulated delivery pen.

Regarding claims 1-6 and 13-17, Grayson discloses a device for delivering a substance to the bone comprising a bone screw (10) that is cannulated therethrough with one or more fenestrations (41) disposed along its length with an insert disposed (60) inside the bone-screw shaft with the insert having one or more fenestrations to

Art Unit: 3763

provide a delivery pathway (col 5, ln 10-15) (Figures 1-3 and 6-8). The insert can be situated to cover or partially cover one or more fenestrations (col 5, ln 1-20) and wherein the bone screw is self-tapping and capable of fixation (col 3, ln 58-68). The insert and screw can be composed of a variety of materials such as any well-known metals like titanium, stainless steel or other materials known (col 5, ln 15-23).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9-10 are rejected under 35 U.S.C 103(a) as being unpatentable over Grayson in view of Miller et al. (6,228,088). Grayson meets the claim limitations as described above except for a substance reservoir that is attached to the one end of the bone screw and implanted subcutaneously.

However, Miller et al. teaches a combination drill bit and intramedullary catheter.

Art Unit: 3763

Regarding claims 9-10, Miller et al. teaches a bone screw (38) that has a reservoir that can be filled with a therapeutic agent (Figure 1) and is can be implanted under the skin (Figure 3).

At the time of the invention, it would have been obvious to add the internal reservoir of Miller et al. to the system of Grayson because the addition of the reservoir would allow for long term treatment and time course treatment. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Miller et al.

Claim Rejections - 35 USC § 103

Claims 11-12 are rejected under 35 U.S.C 103(a) as being unpatentable over Grayson in view of Wigness et al. (5,203,770). Grayson meets the claim limitations as described above except for an implanted pump attached to the end of the bone screw.

However, Wigness et al. teaches a method and apparatus for catheterization.

Regarding claims 11-12, Wigness et al. teaches a bone screw (40) that has a pump (85) attached to the end of the screw for delivery of therapeutic agents (Figures 1-2 and 4-5).

At the time of the invention, it would have been obvious to add the internal pump of Wigness et al. to the system of Grayson et al. because the addition of a internal pump allows for long team controlled delivery of the therapeutic agent to the body. The references are analogous in the art and with the instant invention; therefore, a

Art Unit: 3763

combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Wigness et al.


Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 10/25/06


Christopher D. Koharski
AU 3763


NICK LUCCHESI
SUPERVISOR
571-272-4977